K070383

JUN 22 2007

Enzymatic Creatinine Assay **Product Cat. No. 265-30, 265-50**

510(K) SUMMARY

Introduction: This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitter:

Diagnostic Chemicals Limited
16 McCarville Street
Charlottetown, P.E.I.
Canada C1E 2A6
(Tel:) (902)566-1396
(Fax:) (902)566-2498

Contact Person: Debbie Murray

Date Prepared: April 11, 2007

Device Name: Tradename: Enzymatic Creatinine Assay
FDA Regulation Name: 862.1225 Creatinine Test System
FDA Product Code: JFY

Predicate Device: Roche Diagnostics Corp. Creatinine Plus (K003261)

Device Description: The Enzymatic Creatinine Assay contains an in vitro diagnostic reagent system intended for the quantitative determination of creatinine in serum, plasma and urine. Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes. Reagent is a two-part liquid in plastic bottles packaged in the appropriate box.

Intended Use For the IN VITRO quantitative determination of creatinine in serum, plasma and urine.

Comparison to Predicate Device:

Description of the Item Being Compared:

Enzymatic in vitro assay for the direct quantitative determination of creatinine in human serum, plasma and urine using Roche automated clinical chemistry analyzers.

Creatinine Plus Reagent: R1 TAPS buffer: 30 mmol/L, pH 8.1; creatinase ≥ 333 µkat/L; sarcosine oxidase ≥ 133 µkat/L; ascorbate oxidase ≥ 33 µkat/L; HTIB: 5.9 mmol/L; detergents; preservative.

Creatinine Plus Reagent: R2 TAPS buffer: 30 mmol/L, pH 8.0; creatininase ≥ 500 µkat/L; peroxidase ≥ 16.7 µkat/L; 4-aminophenazone: 2.0 mmol/L; potassium hexacyanoferrate (II): 163 µmol/L; detergent; preservative.

Similaries:

The submission device and the predicate device have the same intended use.

The submission device and the predicate device are both provided in a ready to use liquid format.

The submission device and the predicate device both use enzyme-linked steps using sarcosine oxidase and peroxidase to produce a colored product.

Differences:

There are no differences.

Comments on Substantial Equivalence:

Testing results demonstrate that the Enzymatic Creatinine Assay is equivalent to the predicate device. Method comparison results provided the following:

Serum

Deming regression using NCCLS EP9-P.

A comparison was made between this method and a similar enzymatic method using 40 samples ranging from 0.7 to 31.2 mg/dL. The correlation coefficient was 1.0000. Linear regression analysis gave the following equation:

This method = 1.033 (reference method) - 0.13 mg/dL.

Urine

Deming regression using NCCLS EP9-P.

A comparison was made between this method and a similar enzymatic method using 40 samples ranging from 13.5 to 141.7 mg/dL. The correlation coefficient was 0.9995. Linear regression analysis gave the following equation:

This method = 1.041 (reference method) +1.06 mg/dL.

Plasma

Deming regression using NCCLS EP9-P.

A comparison was made between plasma and serum using 33 samples ranging from 0.61-27.04 mg/dL. The correlation coefficient was 0.9997. Linear regression analysis gave the following equation:

Plasma = 1.006 (serum) - 0.03 mg/dL.

Conclusion: Diagnostic Chemicals Limited's Enzymatic Creatinine Assay is substantially equivalent in principle and performance to the predicate product.

Debbie Murray,
External Regulatory Affairs Coordinator
Diagnostic Chemicals Limited
Diagnostic Division

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 22 2007

Diagnostic Chemicals, Ltd.
c/o Ms. Debbie Murray
External Regulatory Affairs Coordinator
16 McCarville St.
Charlottetown, Price Edward Island
C1E 2A6 Canada

Re: k070383

Trade Name: Enzymatic Creatinine Assay (265 series)
Regulation Number: 21 CFR 862.1225
Regulation Name: Creatinine Test System
Regulatory Class: Class II
Product Code: JFY
Dated: April 11, 2007
Received: May 04, 2007

Dear Ms. Murray:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K070383

Device Name: Enzymatic Creatinine Assay (265 Series)

Indications For Use:

Reagent

The Diagnostic Chemicals Limited Enzymatic Creatinine Assay is for the quantitative determination of creatinine in serum, plasma and urine. Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes. This device is intended for professional use and IN VITRO diagnostic use only.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

(Optional) K070383